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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/771,928	02/04/2004	Jerry A. Douglas	N9914	3499

7590 03/27/2007

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EXAMINER	
BARHAM, BETHANY P	
ART UNIT	PAPER NUMBER
1615	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/27/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/771,928	DOUGLAS, JERRY A.	
	Examiner	Art Unit	
	Bethany P. Barham	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☒ Claim(s) *14 and 20* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *05/06/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Summary

Receipt of IDS filed on 05/06/2004 is acknowledged. Claims 1-20 are pending. Claims 1-20 are rejected.

Objections

Claim 20 objected to under 37 CFR 1.75 as being a substantial duplicate of claim 14. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Double Patenting

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101, which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 1-6 provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 5-10 of copending Application No. 11/238,449. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887,225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-15 and 19-20 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 9-13, and 16-19 of US 5,174,990, 1, 8-12, and 15-17 of US 5,310,546. Although the conflicting claims are not identical, they are not patentably distinct from each other because they overlap

in subject matter pertaining to a composition comprising disodium EDTA in overlapping ranges, hydrogen peroxide (an oxidant) in overlapping ranges, zinc chloride in overlapping ranges, sodium citrate, sodium lauryl sulfate, and glycerin in amounts as claimed in the instant application, the pH of the compositions is overlapping and the method of preparation disclosed is similar in its steps. All compositions are drawn to use on skin or mouth areas.

Claims 12 and 15-19 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 11-16 of copending application 11/238, 449. Although the conflicting claims are not identical, they are not patentably distinct from each other because they overlap in subject matter pertaining to a method of treating inflammatory response comprising a composition of precursor salts and at least one precursor oxidant mixed stepwise to produce a solution with zinc, sodium, citrate, and chloride ions for treating at least once daily, three to five times per day, applying the composition to an area that has dermatological inflammatory response, and applying to skin or tissue area.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-11, 14-15 and 19-20 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,104,644 ('644).

The limitations of claims 1-6 are taught by '644:

- '644 is a mouthrinse preparation contains about 0.5 to about 3 % hydrogen peroxide, zinc chloride, sodium lauryl sulfate, and sodium citrate in amounts sufficient to provide antiplaque, antibacterial, astringent, and anticoagulant properties (abstract). '644 also teaches including disodium EDTA, glycerin, and citric acid (col. 9, lines 36-45). The compositions of '644 are taught to produce a final desired pH of about 3.5 to about 4.0, or other variants have pHs of about 3.5-5.5 and 6-7 (col. 9, line 5-13).
- '644 teaches in Example 1 a mouth rinse comprising (all in % by weight) 0.03-0.05 disodium EDTA, 0.04-0.08 sodium lauryl sulfate, 0.03-0.06 sodium citrate, 0.02-0.04 zinc chloride and 0.05-3 hydrogen peroxide (a 3% soln as shown in the 1st table). Example 1 also teaches glycerin 2.5-3.5% and citric acid 0.01-0.05% by weight and a pH of 3.5-4.0 (as shown in the 2nd table).

The limitations of claims 7-11, 14-15 and 19-20 are taught by '644:

- Claims 1-6 of '644 teach the limitations of the instant claims 7, 9-10, 14 and 20 except for the EDTA, which is shown in all the examples of '644 and is found overlapping with the instant applications' range in Example 1 as shown above, as are all the ingredients claimed shown in overlapping ranges with the instant

application in example 1. Further, '644 teaches citric acid and pH of instant claims 8 and 11 in example 1 as shown above.

- The composition of '644 it taught to control etiological factors, microbiota, local factors, plaque and inflammation, and to kill bacteria, restore the edematous tissue to the normal state, check inflammatory processes responsible for gingivitis and heal hemorrhagic tissue (col. 1, 9-25). Also, '644 is taught to contain components that are known astringents and anti-inflammatory agents (col. 6, lines 59-65) and that using a rinse in oral irrigation that has heavy concentration of oxygen, antimicrobial agents, anti-inflammatory agents and anti-surface tensions agents will impede the growth process of disease causing microbiota and furnish oxygen for the growth of normal flora of the oral cavity, helping the tissues of the oral cavity maintain a normal host-parasite balance (col.3, line 67-col. 4, line 6).

Claims 1-6 are rejected under 35 U.S.C. 102(b) as being anticipated by US 6,086,856 ('856).

The limitations of claims 1-6 are taught by '856:

- '856 teach oral hygiene formulations comprising foaming surfactants as mouthwashes, rinses and dentifrices containing one or more antimicrobial, anti-plaque, and anti-cariogenic agents (abstract)
- Example 5 teaches a hydrogen peroxide based aqueous mouthwash comprising 0.6% H_2O_2, 0.02% zinc chloride, 0.03% sodium citrate, 0.02% citric acid and

0.2% sodium lauryl sulfate all in weight percent as described in example 2 of US 5,174,990 using the method of Example 1 of the patent and the ingredients and their concentrations are substantially as given is col. 6 of the patent except sodium lauryl sulfate, which is recited above (col. 11, lines 33-45).

Claims 1-5, 7-11, 14-15 and 19-20 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,174,990 ('990) or US 5,310,546.

The limitations of claims 1-5 are taught by '990 or '546:

- '990 or '546 is a mouthrinse preparation containing between about 0.25 and about 0.65 % hydrogen peroxide, about 0.1% zinc chloride, at least about 0.0012% sodium citrate and at least about 0.03% sodium lauryl sulfate, and at least about 0.006% citric acid (abstract, claim 1). '990 also teaches glycerin in the amount of about 1.8- about 9% (col. 4, lines 20-21, claims 9-10), disodium EDTA from about 0.022 to 0.1% (col. 4, lines 24-26, claims 12-13) and a pH from about 3.5 to about 4.5 (col. 3, lines 45-48). Further, '990 or '546 claims 16 and 17 claim ingredients within the instant applications' ranges.
- Specifically, '990 or '546 Example 2 teaches a mouthrinse comprising 0.595% H_2O_2, 0.016% zinc chloride, 0.024% sodium citrate, 0.0158% citric acid, 0.044% disodium EDTA, and 0.06% sodium lauryl sulfate all in weight percent, with a pH of 3.925.

The limitations of claims 7-11, 14-15 and 19-20 are taught by '990 or '546:

- '990 or '546 teach disodium EDTA from about 0.022 to 0.1% (col. 4, lines 24-26, claims 12-13) and between about 0.25 and about 0.65 % hydrogen peroxide (col. 3, lines 2-3), about 0.005 and about 0.1% zinc chloride (col. 3, lines 15-17), at least about 0.0012% and up to about 0.2% or greater sodium citrate (col. 3, lines 47-48) and at least about 0.03% sodium lauryl sulfate, in ratio with zinc chloride in the range of from about 2 to 1 to about 8 to 1 (col. 3, lines 35-40), and always greater than about 0.005% citric acid to maintain the pH of about 3.5 to about 4.5 (col. 3, lines 53-59).
- Example 3 of '990 or '546 teaches that the composition of the invention is capable of reducing inflammation in patients 100% of the time when administered to their mouths. Example 4 of '990 or '546 shows that the composition kills bacteria and/or inhibits their growth.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 15-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,104,644 in view of US 6,086,856.

The limitations of claims 15-19 are taught by '644 in view of '856:

- '644 is taught above.
- '644 does not teach a method of applying at least once a day and 3 to 5 times daily of applying to an inflamed surface.
- '856 teaches in Example 8 that the system is well suited for the delivery of non-ingestible expectoratable formulations to the oral cavity as medicaments, used for cleansing minor wound or irritations of the mouth or gums, for example, a small amount of the medicated e.g. H_2O_2 containing foam is dispensed and applied to the affected area, and that the foam can be used up to 4 times daily (after meals and at bedtime) (col. 12, lines 18-30).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of '644 and '856 since both teach H_2O_2 based mouthwash systems for treating irritation and inflammation. One of ordinary skill in the art would have been motivated to combine since the ranges set forth in example 1 and the claims of '644 encompass the example 5 of the '856. Thus one seeking how often to use the medicament would look to '856, which discloses a proper method of use.

Claims 12-13 are rejected under 35 U.S.C. 103(a) as being anticipated by US 5,174,990 ('990) or US 5,310,546 ('546).

The limitations of claims 12-13 are taught by '990 or '546:

- '990 or '546 Example 1 teaches a zinc chloride solution is prepared by adding zinc chloride to deionized water and allowing the heat to dissipate from the solution after mixing.
- Then a remaining ingredient solution is prepared in deionized water of disodium EDTA, sodium citrate, sodium lauryl sulfate, etc, and is mixed with the zinc chloride solution and allowing the heat to dissipate from the solution after mixing.
- Lastly the hydrogen peroxide solution was added to the previous solution and mixed for several minutes to form a stabilized mouthrinse containing hydrogen peroxide (col. 5, lines 30-62, claim 18).
- It is the examiner's opinion that one of ordinary skill in the art (PhD level) at the time the invention was made would know how long to wait in order to allow the heat to dissipate from the solution or the solution to cool after mixing has occurred, or to vary mixing times of the composition.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bethany Barham whose telephone number is (571)-272-6175. The examiner can normally be reached on Monday to Friday; 8:30 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Bethany Barham
Art Unit 1615

MICHAEL P. WOODWARD
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Comparable to Form PTO-1449

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INFORMATION DISCLOSURE CITATION
(Use several sheets if necessary)

Atty. Docket No.	Serial No.
N9914 Customer No. 23456	10/771,928
Applicant: Jerry A. Douglas	
Filing Date: February 4, 2004	Group: Unknown

Examiner Initial		Document No.	Date	Name	Class	Subclass	Filing Date If Appropriate
/BB/		3,887,704	June 3, 1975	Lichtenstein	424	145	
		4,160,821	June 10, 1979	Sipos	424	145	
		4,226,851	October 7, 1980	Sompayrac	424	53	
		4,325,939	April 20, 1982	Shah	424	55	
		4,339,432	July 13, 1982	Ritchey, et al	424	54	
		4,425,325	January 10, 1984	Ritchey, et al	424	54	
		4,477,438	October 16, 1984	Willcockson, deceased et al.	424	130	
		4,853,213	August 1, 1989	Thame	424	58	
		4,980,152	Dec. 25, 1990	Frazier, et al.	424	52	
		4,992,259	February 12, 1991	Schiraldi et al.	424	49	
		5,002,970	March 26, 1991	Eby, III	514	494	
		5,104,644	April 14, 1992	Douglas	424	53	
		5,143,720	September 1, 1992	Lopes	424	55	
		5,174,990	Dec. 29, 1992	Douglas	424	53	
		5,310,546	May 10, 1994	Douglas	424	53	
		5,372,802	Dec. 13, 1994	Barrow, et al.	424	52	
		5,665,332	September 9, 1997	Mundschenk et al.	424	49	
		5,707,610	January 13, 1998	Ibsen, et al.	424	49	
		5,855,873	January 5, 1999	Yam	424	49	
		5,948,390	September 7, 1999	Nelson, et al.	424	54	
		6,086,856	July 11, 2000	Saferstein, et al.	424	58	
		6,348,187	February 19, 2002	Pan, et al.	424	53	
		6,409,992	June 25, 2002	Kleinberg, et al.	424	49	
		6,592,852	July 15, 2003	Ryles, et al.	424	49	
		MISCELLANEOUS DOCUMENTS					
		Published Patent Application US 2002/0081270A1, June 27, 2002, by Delli Santi, et al.					
		Published Patent Application US 2002/0182267 A1, December 5, 2002, by Kleinberg, et al.					
		Synopsis of the Concept and Theory of Prevention Mouth Rinse, Prevention Laboratories, L.L.C., 66 pages (not later than February 3, 2003.)					
		Prevention Mouth Rinse Scientific Data, Prevention Laboratories, L.L.C., 52 pages (not later than February 3, 2003.)					
		Prevention Everyday Applied to Skin Rash, Prevention Laboratories, L.L.C., 1 page (not later than February 3, 2003.)					
		A Complete Balanced System, Prevention Laboratories, L.L.C., 65 pages (not later than February 3, 2003.)					

Examiner: /Bethany Barham/ Date Considered 03/12/2007

*Examiner: Initial if citation considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Comparable to Form PTO-1449 U.S. Department of Commerce Patent & Trademark Office INFORMATION DISCLOSURE CITATION (Use several sheets if necessary)	Atty. Docket No. N9914 Customer No. 23456	Serial No. 10/771,928
	Applicant Jerry A. Douglas	
	Filing Date February 4, 2004	Group Unknown

Examiner Initial		Document No.	Date	Name	Class	Subclass	Filing Date If Appropriate

MISCELLANEOUS DOCUMENTS

/BB/		*Triumph Pharmaceuticals, Inc.*, online catalog, www.trioral.com/products/rinse.php, TriOral BreathCure, 2 pages (May 3, 2004)
↓		*Triumph Pharmaceuticals, Inc.*, online catalog, www.trioral.com/trioral/faq_rinse.php, Frequently Asked Questions TriOral BreathCure, 12 pages (May 3, 2004)
		Tender Corporation, www.tendercorp.com/afterbite.html, After Bite, 2 pages (March 24, 2004)

Examiner: /Bethany Barham/ Date Considered 03/12/2007

*Examiner: Initial if citation considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Notice of References Cited	Application/Control No. 10/771,928	Applicant(s)/Patent Under Reexamination DOUGLAS, JERRY A.	
	Examiner Bethany P. Barham	Art Unit 1615	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A	US-5,104,644	04-1992	Douglas, Jerry A.	424/53
*	B	US-5,174,990	12-1992	Douglas, Jerry A.	424/53
*	C	US-5,310,546	05-1994	Douglas, Jerry A.	424/53
*	D	US-6,086,856	07-2000	Saferstein et al.	424/58
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

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